Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995 persons are required to respond to a collection of information unless it contains a valid OMB control number.

1001.			· /			
	Substitute it	Month 198	/PTO		Complete if Known	- IEOEI
	INFORMATI	ON DISCLO	SURE	Application Number	09/937,840	Mari
	STATEMEN	T BY APPL	CANT	Filing Date	09/26/2001	TEO MAY 1 4 2
				First Named Inventor	Patrick Soon-Shiong	'A WH CENT
				Group Art Unit	1614	BIVIE A
	(use as many s	sheets as ne	cessary)	Examiner Name	Unknown	
neet	1	of	4	Attorney Docket Number	ABI1550-1 (071243-1404)	

				U.S. PATENT DOCUMENTS	3	
	Cite No.1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
Examiner Initials*		Number Kind Code ² (if known)	Cited Document MM-DD-YYYY			
	A1	5,041,292		Feijen	Aug. 20, 1991	
Y	A2	5,631,018		Zalipsky et al.	May 20, 1997	
	A3	5,714,166		Tomalia et al.	Feb. 3, 1998	
	A4	5,723,147		Kim et al.	Mar. 3, 1998	
	A5	5,756,537		Gill	May 26, 1998	
	A6	5,766,627		Sankaram et al.	Jun. 16, 1998	
111	A7	5,772,992		Bauer et al.	Jun. 30, 1998	
71	A8	5,789,248		Fodstad et al.	Aug. 4, 1998	
- \	A9	6,066,668		Hausheer et al.	May 23, 2000	
						
	-					

				F	OREIGN PATENT DOCUMEN	T\$	•	
Examiner Initials*	Cite No. ¹	Fr Office	oreign Patent D	Ocument Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
M	A10	WO	94/06422		Government of the United States as represented by The Secretary, Department of Health and Hnman Services	March 31, 1994		
								-

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶				
em	A11	International Search Report for PCT Application No. PCT/US00/10849					
m	X 12	Supplementary European Search Report for European Patent Application No. EP 00 92 8296.					

Examiner Signature	am	Date Considered	5-24-04
-----------------------	----	--------------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995 persons are required to respond to a collection of information unless it contains a valid OMB control number.

Sheet

Substitute (Substitute B/PTO Complete if Known 09/937,840 **Application Number** INFORMATION DISCLOSURE STATEMENT BY APPLICANT 09/26/2001 **Filing Date** Patrick Soon-Shiong First Named Inventor **Group Art Unit** 1614 Unknown (use as many sheets as necessary) **Examiner Name** of Attorney Docket Number ABI1550-1 (071243-1404)

		NON PATENT LITERATURE DOCUMENTS	
Examiner nitials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т
M	A13	Arbuck et al., "Clinical Development of Taxol." Journal of the National Cancer Institute Monographs No. 15, p. 11-24, 1993.	
	A14	Dorr, "Pharmacology of the Taxanes." Pharmacotherapy, 17:965-1045, 1997.	
	A15	Eisenhauer et al., "European-Canadian randomized trial of Paclitaxel in relapsed ovarian cancer: high-dose versus low-dose and long versus short infusion." Journal of Clinical Oncology, 12:2654-2666, 1994.	
	A16	Fennelly et al., "Phase I and pharmacologic study of Paclitaxel administered weekly in patients with relapsed ovarian cancer." Journal of Clinical Oncology, 15:187-192, 1997.	
	A17	Fletcher et al., "Antinociceptive effect of bupivacaine encapsulated in Poly(D,L)-Lactide-Co-Glycolide microspheres in the acute inflammatory pain model of carrageenin-injected rats." Anesth. Analg., 84:90-94, 1997.	
	A18	Gianni et al., "Nonlinear pharmacokinetics and metabolism of Paclitaxel and its pharmacokinetic/pharmacodynamic relationships in humans." Journal of Clinical Oncology, 13:180-190, 1995.	
	A19	Greco et al., "One-hour Paclitaxel infusions: review of safety and efficacy." The Cancer Journal, 5: 179-191, 1999.	
	A20	Holmes et al., "Final Results: Randomized phase III trial of Paclitaxel by 3-hour versus 96-hour infusion in patients (PT) with MET breast cancer. The long and short of it." Meeting Abstract. Proceedings of the American Society of Clinical Oncology, 16:110a, 1998.	
	A21	Holmes et al., "Phase III trial of pactitaxel (P) administered over 3- or 96-hr for metastatic breast cancer (MBC)." Meeting Abstract. Proceedings of the American Society of Clinical Oncology, 15:106a, 1996.	
V	A22	Hainsworth et al., "Carcinoma of unknown primary site: Treatment with 1-hour Paclitaxel, Carboplatin, and extended-schedule Etoposide." Journal of Clinical Oncology, 15:2385-2393, 1997.	

Examiner Signature	cm	Date Considered	5-24-04

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁵Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

no persons are required to respond to a collection of information unless It contains a valid OMB control Under the Paperwork

number.

Sheet

Complete if Known Substitute for form 14 09/937,840 **Application Number** INFORMATION DISCLOSURE STATEMENT BY APPLICANT 09/26/2001 Filing Date First Named Inventor Patrick Soon-Shiong Group Art Unit 1614 (use as many sheets as necessary) **Examiner Name** Unknown of Attorney Docket Number ABI1550-1 (071243-1404) 3 4

NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Cite Examiner T⁶ item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), Initials* No. publisher, city and/or country where published. Hainsworth et al., "Paclitaxel administered by a 1-hour infusion: A Phase 1-11 trial comparing two A23 schedules." The Cancer Journal from Scientific American, 1:281-287, 1995. A24 Hainsworth et al., "Paclitaxel by 1-hour infusion: An Active drug in metastatic non-small-cell lung cancer." Journal of Clinical Oncology, 13:1609-1614, 1995. Hainsworth et al., "Paclitaxel, carboplatin, and extended-schedule etoposide in the treatment of small-cell A25 lung cancer: comparison of sequential phase II trials using different dose-intensities." Journal of Clinical Oncology, 15:3464-3470, 1997. Huizing et al., "Pharmacokinetics of Paclitaxel and metabolites in a randomized comparative study in A26 platinum-pretreated ovarian cancer patients." Journal of Clinical Oncology, 11:2127-2135, 1993. A27 Kearns et al., "Paclitaxel pharmacokinetics and pharmacodynamics." Seminars in Oncology, 22:16-23, 1995. Klaassen et al., "Phase I study with a weekly 1 h infusion of paclitaxel in heavily pretreated patients with A28 metastatic breast and ovarian cancer." European Journal of cancer, 32A: 547-549, 1996. A29 Langer et al., "Paclitaxel (P) by 1 or 24 hour (HR) infusion combined with carboplatin @ in advanced nonsmall cell lung carcinoma (NSCLC): a comparative analysis." Meeting abstract. Proceedings of the American Society of Clinical Oncology, 16:45a, 1997. A30 Lopes et al., "Cell kill kinetics and cell cycle effects of taxol on human and hamster ovarian cell lines." Cancer Chemotherapy and Pharmacology, 32:235-242, 1993.

بالسائن السار			
Examiner Signature	CM	Date Considered	5-24-04

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria. Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2See attached Kinds of U.S. Patent Documents. 3Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, net persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute 09/937,840 INFORMATION DISCLOSURE **Application Number** Filing Date STATEMENT BY APPLICANT 09/26/2001 Patrick Soon-Shiong **First Named Inventor** 1614 Group Art Unit **Examiner Name** Unknown (use as many sheets as necessary) Attorney Docket Number ABI1550-1 (071243-1404) of 4 4 Sheet

		NON PATENT LITERATURE DOCUMENTS	-
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	76
M	A31	Obtsu et al., "Clinical pharmacokinetics and pharmacodynamics of paclitaxel: A 3-hour infusion versus a 24-hour infusion." Clinical Cancer Research, 1:599-606, 1995.	
	A32	Onetto et al., "Overview of taxol safety." Journal of the National Cancer Institute, Monographs No. 15, p. 131-139, 1993.	
	A33	Seidman et al., "One-hour paclitaxel via weekly infusion: Dose-density with enhanced therapeutic index." Oncology, Vol. 12, No. 1, Supplement No. 1, p. 19-22, 1998.	
	A34	Sonnichsen et al., "Saturable pharmacokinetics and paclitaxel pharmacodynamics in children with solid tumors." Journal of Clinical Oncology, 12: 532-538, 1994.	

$\alpha \alpha \alpha$.	Date	- nl nl
	Considered	5-24-04
	A Committee of the Comm	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.